UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ESPERION THERAPEUTICS, INC., Plaintiff, -against- DAIICHI SANKYO EUROPE GMBH, Defendant.	No. 1:23-cv-02568-ER **FIRST AMENDED COMPLAINT**

Plaintiff Esperion Therapeutics, Inc. ("Plaintiff" or "Esperion"), by its attorneys, Gibson, Dunn & Crutcher LLP, for its First Amended Complaint for declaratory relief against Defendant Daiichi Sankyo Europe GmbH ("DSE"), upon knowledge as to itself and its conduct and upon information and belief as to all other matters, alleges as follows:

INTRODUCTION

1. Esperion is a trailblazing pharmaceutical company that manufactures innovative drugs for the treatment of cardiovascular disease. In 2019, Esperion granted DSE an exclusive license to sell Esperion's drugs in Europe. In exchange, DSE agreed to pay Esperion more than $1 billion in royalties and milestone payments tied to certain regulatory and sales events. The regulatory milestone payment, in the amount of $300 million, will be due when Esperion receives a "cardiovascular risk reduction" label in Europe in the first half of 2024. DSE recently announced it will not make the $300 million milestone payment that the contract requires. On information and belief, DSE knows its position is wrong and is repudiating the agreement in bad faith, in a transparent attempt to drive down Esperion's stock price and pressure it to re-negotiate the financial terms of the parties' license agreement. Esperion refuses to acquiesce to DSE's

commercially dishonest tactics. Instead, a prompt judicial declaration of the rights and obligations of the parties is urgently needed to resolve this substantial and concrete controversy between the parties. Esperion brings this action to obtain a judicial declaration, on an expedited basis, that DSE's bad-faith interpretation of the parties' agreement is wrong and that DSE is contractually required to make the $300 million payment upon regulatory approval.

2. Esperion is a Michigan-based company focused on the development of bempedoic acid, a first-in-class drug essential to patients with high LDL cholesterol (commonly referred to as "bad" cholesterol). Statins are the most common treatment for patients with high LDL cholesterol. But statins do not meet the health needs of millions of patients around the world who are "statin intolerant," or who otherwise cannot reach their LDL cholesterol goals with statins alone. Esperion developed bempedoic acid as a treatment option for statin intolerant patients to lower LDL cholesterol and reduce the risk of heart disease. Esperion's innovative bempedoic acid drugs have been approved by both the FDA and its European equivalent with labeling indications for the successful reduction in cholesterol.

3. DSE is the European affiliate of Daiichi Sankyo Company, Ltd., a large pharmaceutical company based in Japan. In January 2019, Esperion and DSE entered into the License and Collaboration Agreement ("Agreement"), in which Esperion gave DSE exclusive rights to market and sell its bempedoic acid drugs ("LDL Treatments") in Europe—an exclusive right potentially worth hundreds of millions of dollars. At the time DSE secured this exclusive right, Esperion had completed the first phases of a landmark clinical trial, the CLEAR Outcomes Study, that would show bempedoic acid not only reduced cholesterol, but materially reduced the risk of heart attacks, strokes, and other adverse cardiovascular events. Knowing the market for Esperion's LDL Treatments was on the verge of an unprecedented expansion, DSE sought to lock

up the license to these valuable LDL Treatments before its competitors beat them to it. After signing the Agreement, DSE issued a press release touting its "great confidence" in the LDL Treatments, "which will address a critical unmet need for patients."

4. In exchange for these exclusive and valuable rights, DSE agreed to pay Esperion royalties and up to $900 million in regulatory and commercial milestone payments. Section 9.2 of the Agreement requires DSE to make a "regulatory milestone payment" to Esperion when it obtains regulatory approval of a label including "cardiovascular risk reduction." Agreement § 9.2 (attached as Exhibit A).[1] Esperion is entitled to a $300 million milestone payment if the "cardiovascular risk reduction" rate is demonstrated to be greater than 20%, and a $200 million milestone payment if the "cardiovascular risk reduction" rate is demonstrated to be between 15% and 20%. *Id.* The "cardiovascular risk reduction" rate—and the corresponding amount of the milestone payment—is based on the results of the CLEAR Outcomes Study.

5. The milestone payments were a critical and material financial term in the parties' contractual relationship. Esperion began developing the LDL Treatments in 2008, and had taken substantial risk by investing years and many hundreds of millions of dollars in developing these drugs. DSE was obtaining exclusive rights to commercialize the LDL Treatments in the final stages of the development process—when the drugs were nearly ready to go to market. The financial rewards for the risk Esperion had taken could be enormous: Esperion projected that with a "cardiovascular risk" reduction label, sales of the LDL Treatments in Europe could exceed $1

[1] Certain portions of the Agreement are redacted, pursuant to the Agreement's confidentiality provision. *See* Agreement §§ 1.24, 7.1.1. As also required under the Agreement, Esperion sought DSE's consent to make the entire Agreement public through this filing. DSE refused to give its consent. Accordingly, until the issue of sealing is resolved by the Court or by agreement of the parties, Esperion has filed a copy of the Agreement disclosing only those portions that have previously been made public. An entirely unredacted copy of the Agreement has been filed under seal.

billion annually. It was critical to Esperion that the parties' deal reward Esperion for the risk it had taken and the substantial resources it already had invested in developing the LDL Treatments.

6. The CLEAR Outcomes Study concluded in November 2022 and the results were spectacular. The study demonstrated Esperion's bempedoic acid drug reduces "cardiovascular risk" by more than 20%, including a 27% reduction in non-fatal heart attacks and 23% reduction in the composite of nonfatal and fatal heart attacks. The study also demonstrated a 19% reduction in coronary revascularization (severe blockage of the arteries), 15% reduction in fatal and nonfatal strokes, 15% reduction in MACE-3 (a composite of cardiovascular death, nonfatal heart attacks, or nonfatal stroke), and 13% reduction in MACE-4 (a composite of cardiovascular death, nonfatal heart attacks, nonfatal stroke, or coronary revascularization).

7. On December 7, 2022, Esperion announced the top-line results of the CLEAR Outcomes Study. On March 4, 2023, Esperion presented the full study results at the American College of Cardiology ("ACC") annual conference and published the results in the *New England Journal of Medicine*. The medical community quickly recognized the CLEAR Outcomes Study results as a landmark achievement in the treatment of statin intolerant patients. After the publication of the CLEAR Outcomes Study results, the International Lipid Expert Panel (ILEP) published positive recommendations for the use of bempedoic acid in the management of lipid disorders and cardiovascular risk. In the four weeks after the announcement of the study results, the number of prescriptions written for patients switching to or starting the LDL Treatments increased by 88%.

8. By the time Esperion publicly announced the CLEAR Outcomes Study results on March 4, 2023, Esperion had been discussing those results with DSE, under strict confidentiality, for months. On March 8, 2023, DSE informed Esperion—for the first time—that it will not make

the contractually-required $300 million payment to Esperion. DSE asserted that the regulatory milestone payment was contingent on only MACE-4 results, not any of the other key measures of cardiovascular risk in the CLEAR Outcomes Study. According to DSE, because the CLEAR Outcomes Study demonstrated a risk reduction rate for MACE-4 less than 15%, it will not make any regulatory milestone payment.

9. DSE's position is contrary to the clear terms of the Agreement and the drafting history of the Agreement, and is a bad-faith pretext to evade its $300 million payment obligation.

10. ***The Unambiguous Terms of the Agreement***. The Agreement is clear. It requires "cardiovascular risk reduction" of 20% to trigger DSE's $300 million regulatory milestone payment. Agreement § 9.2. "Cardiovascular risk reduction" is ***not*** a defined term in the Agreement, which reflects the parties' mutual intent and understanding that these words be given their plain and ordinary meaning. Nothing in the Agreement ties Esperion's regulatory milestone payment to MACE-4 specifically, rather than any of the other key measures of cardiovascular risk. ***MACE-4 is not even mentioned*** in the section of the Agreement detailing DSE's regulatory milestone payment obligations or the rest of the Agreement. If the parties had intended to restrict "cardiovascular risk reduction" to only MACE-4, as DSE now asserts—or to have given it any other technical or specialized meaning—they could have and would have said so. DSE's myopic reading of the Agreement is contrary to its plain language and basic canons of contract interpretation.

11. ***The Negotiating and Drafting History of the Agreement***. Because the language of Section 9.2 is unambiguous, there is no need to go beyond the four corners of the Agreement. In any event, the extrinsic evidence is fatal to DSE's reading of the Agreement. During the negotiation and drafting of the Agreement, DSE proposed making Esperion's regulatory milestone

payment contingent on a reduction in the specific MACE-4 endpoint—the contract term DSE now says was agreed to. ***But Esperion expressly rejected this proposed contractual term and DSE agreed to remove it***. In other words, the parties specifically considered adding language to the Agreement to make MACE-4 risk reduction a specific requirement for Esperion to receive the full milestone payment and decided ***not*** to add this requirement. DSE's position that MACE-4 is the contractual north star is a naked attempt to re-trade the parties' deal and obtain through bad-faith repudiation what it failed to achieve at the negotiating table.

12. DSE's motive is clear. At the time of DSE's bad-faith repudiation, Esperion was on the eve of closing an offering to raise capital. DSE knew that given the materiality of the $300 million payment, Esperion, a publicly traded company on NASDAQ, would be required to publicly disclose DSE's repudiation of its payment obligation to the investing public. On information and belief, DSE timed its repudiation to put maximum financial pressure on Esperion, in a transparent attempt to drive down Esperion's stock price and pressure it to re-negotiate the financial terms of the parties' license agreement.

13. DSE's repudiation inflicted immediate and substantial harm to Esperion. When DSE's repudiation became public, Esperion's stock plummeted, dropping 54% in a single day. The harm to Esperion is ongoing and its stock price remains below $2 per share.

14. In this action, Esperion seeks prompt declaratory relief to stop DSE's unlawful conduct. DSE has said it will not pay Esperion the $300 million regulatory milestone payment it is owed. Esperion seeks a judicial declaration that DSE is required to make this payment upon regulatory approval.

PARTIES

15. Esperion is a pharmaceutical company incorporated in Delaware and has its

principal place of business in Ann Arbor, Michigan. Esperion has more than 200 employees in the United States. Esperion is focused on developing and commercializing accessible, oral, once-daily, non-statin medicines for patients with elevated LDL cholesterol. Esperion is publicly traded on NASDAQ (ESPR).

16. DSE is a limited liability company in Germany with its principal place of business in Munich, Germany. DSE is a wholly owned affiliate of Daiichi Sankyo Company, Ltd., which is a global pharmaceutical company headquartered in Tokyo, Japan. Daiichi Sankyo, Ltd. has two U.S. affiliates: Daiichi Sankyo, Inc. and American Regent, Inc.

JURISDICTION AND VENUE

17. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) because there is complete diversity of citizenship among the parties and the amount in controversy exceeds seventy-five thousand dollars ($75,000), exclusive of costs and interest.

18. This Court has personal jurisdiction over DSE because DSE consented to the jurisdiction of this Court in the Agreement. Section 14.4 of the Agreement provides that "[e]ach Party by its execution hereof . . . hereby irrevocably submits to the jurisdiction of the courts sitting in New York City, New York, for the purpose of any dispute arising between the Parties in connection with this Agreement." Agreement § 14.4.

19. Venue is proper in this District under 28 U.S.C. § 1391 because DSE consented to venue in this District in the Agreement. *See* Agreement § 14.4.

FACTUAL ALLEGATIONS

A. Esperion Develops Innovative, Life-Saving Drug Therapies For Patients with High Cholesterol Who Lack Other Effective Treatment Options.

20. Since its founding in 2008, Esperion has worked to bring its innovative drug therapies containing bempedoic acid to market. Bempedoic acid is a first-in-class drug, and targets

the synthesis of cholesterol in the liver to help lower LDL cholesterol in patients.

21. High levels of LDL cholesterol can contribute to heart disease and increase risk of heart attacks, strokes, and a variety of other cardiovascular and other health problems. For example, LDL cholesterol can cause atherosclerosis, which is a disease characterized by the deposit of excess LDL cholesterol and other similar lipid-containing particles in the walls of arteries. This process leads to the formation of atherosclerotic plaque lesions in the artery walls. Depending upon their location, continued progression of atherosclerotic plaques can lead to heart attacks, strokes, and peripheral artery disease.

22. Statins, such as Lipitor® and Crestor®, are the typical first line of treatment for patients with high LDL cholesterol. However, many patients are "statin intolerant," meaning they either cannot take statins or cannot tolerate a full daily dose of statins. Statins are taken orally and are biologically active throughout the body. As a result, certain statin intolerant patients experience painful side effects caused by muscle inflammation, including muscle aches, pain, weakness, or cramps when taking statins. Millions of patients in the United States are statin intolerant.[2]

23. Bempedoic acid provides a critical treatment option for statin intolerant patients. Because bempedoic acid is inactive until it enters the liver where it is changed to its active form, it avoids the side effects caused by the activity of statins throughout the body. Once it reaches the liver, bempedoic acid decreases the production of cholesterol and increases the removal of LDL cholesterol from the blood.

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[2] The CDC reports that "[n]early 94 million U.S. adults age 20 or older have total cholesterol levels above 200 mg/dL." *See High Cholesterol Facts*, U.S. Centers for Disease Control and Prevention (Mar. 20, 2023), https://tinyurl.com/yc88yvmb. Additionally, a recent analysis of more than 4 million patients found that an estimated 9.1% of patients are statin intolerant. Bytyçi *et al.*, *Prevalence of statin intolerance: a meta-analysis*, 43 EUR. HEART J. 3212, 3216 (2022).

24. Esperion makes two FDA-approved LDL Treatments containing bempedoic acid. The first is a tablet containing bempedoic acid, first approved in the United States as Nexletol® and in Europe as Nilemdo® in 2020. The other is a tablet containing a combination of bempedoic acid and ezetimibe, first approved in the United States as Nexlizet® and in Europe as Nustendi® in 2020. These LDL Treatments have been sold throughout the United States and Europe since 2020.

25. Nexletol® and Nexlizet® are approved in the United States "as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C."[3] Atherosclerotic cardiovascular disease ("ASCVD") is a slow, progressive disease characterized by the hardening and narrowing of arterial walls. Heterozygous familial hypercholesterolemia ("HeFH") is a genetic condition characterized by impaired cholesterol metabolism and clinically elevated blood cholesterol.

26. Nilemdo® and Nustendi® are approved in Europe for "adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:

- in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin . . . or,

[3] *See* Nexletol®, Highlights of Prescribing Information (Feb. 2020); Nexlizet®, Highlights of Prescribing Information (Feb. 2020).

[Footnote continued on next page]

- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated."[4]

Hypercholesterolaemia refers to high cholesterol, including in patients with HeFH. Mixed dyslipidaemia refers to high levels of triglycerides and LDL cholesterol, usually accompanied by low levels of HDL cholesterol (which is sometimes called "good cholesterol").

B. In 2016, Esperion Launches The CLEAR Outcomes Study To Evaluate Whether Bempedoic Acid Reduces Cardiovascular Risk.

27. In 2016, Esperion, in coordination with the Cleveland Clinic, launched the CLEAR Outcomes Study.[5] The CLEAR Outcomes Study was designed to evaluate whether bempedoic acid reduces the risk of adverse cardiovascular events in statin intolerant patients who have or are at high risk for cardiovascular disease and elevated LDL cholesterol levels. The CLEAR Outcomes Study was a landmark trial and unprecedented in scope. It was a randomized, double-blind, placebo-controlled study and included nearly 14,000 patients at more than 1,200 sites in 32 countries. The CLEAR Outcomes Study began enrolling patients in December 2016 and concluded in November 2022.

28. The CLEAR Outcomes Study evaluated the efficacy of bempedoic acid in reducing the risk of adverse cardiovascular events across seven key measures: (1) MACE-4, a composite of four major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, or coronary revascularization); (2) MACE-3, a composite of three major adverse

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[4] *See* Nilemdo®, European Public Assessment Report, Annex I: Summary of Product Characteristics (Apr. 2022); Nustendi®, European Public Assessment Report, Annex I: Summary of Product Characteristics (Apr. 2022).

[5] The CLEAR Outcomes Study refers to "Evaluation of Major Cardiovascular Events in Patients With, or at High Risk for, Cardiovascular Disease Who Are Statin Intolerant Treated With Bempedoic Acid (ETC-1002) or Placebo (CLEAR Outcomes)" (NCT02993406).

cardiovascular events (cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke); (3) fatal and nonfatal myocardial infarction; (4) coronary revascularization; (5) fatal and nonfatal stroke; (6) cardiovascular death; and (7) all-cause mortality. Although MACE-4 was the "primary efficacy end point" in that it was the primary patient outcome the Study was designed to examine, each of the six "key secondary efficacy end points" provides critical insight into whether bempedoic acid reduces cardiovascular risk.

C. In 2018, Esperion And DSE Negotiate The Agreement And Agree Esperion Is Entitled To A Regulatory Milestone Payment For A "Cardiovascular Risk Reduction" Label.

29. By 2018, Esperion was looking for a partner to commercialize and sell its LDL Treatments in Europe. Esperion had discussions with several sophisticated and market-leading potential partners, including DSE, about an exclusive deal to commercialize Esperion's LDL Treatments in Europe.

30. Milestone payments were a critical financial term for Esperion in these negotiations. Esperion had taken substantial risk in developing the LDL Treatments over a period of several years, and was looking for a partner to commercialize the LDL Treatments in Europe in the final stages of the development process—after Esperion had already spent years investing substantial resources in developing these LDL Treatments. The financial rewards for the risk Esperion already had taken could be lucrative and market-making: Esperion projected that with regulatory approval of a label indicated for "cardiovascular risk reduction," ***annual sales of Esperion's LDL Treatments in Europe could exceed $1 billion***. On the table—for DSE or another potential partner—were the ***exclusive*** rights to this revenue stream. As a result, it was critical to Esperion that any exclusive commercialization deal reward Esperion for the risk it already had taken and the substantial resources it already had invested in developing the LDL Treatments.

31. On November 8, 2018, DSE sent Esperion a statement of interest (the "Statement of Interest") with proposed terms for an exclusive commercialization deal. The Statement of Interest provided that Esperion grant DSE an exclusive license to commercialize Esperion's bempedoic acid products in the European Economic Area and Switzerland. DSE offered to pay Esperion significant consideration for these exclusive commercialization rights, reflecting the substantial value DSE placed on Esperion's LDL Treatments. DSE offered to pay Esperion substantial tiered royalties of up to 25% and up to $900 million in milestone payments based on the achievement of certain commercial and regulatory milestones.

32. Specifically, the Statement of Interest—drafted and proposed by DSE—provided for a regulatory milestone payment "to be paid [to Esperion] upon grant of the MA in the EU for ***Cardio vascular Risk Reduction Label*** in correlation with the relative risk reduction rate described in the below table as the result of the CLEAR Outcome study in the Territory." The Statement of Interest includes the following table describing the relative risk reduction rates required for the regulatory milestone payment:

- Regulatory Milestone payment by Licensee
  Regulatory Milestone to be paid upon grant of the MA in the EU for Cardio vascular Risk Reduction Label in correlation with the relative risk reduction rate described in the below table as the result of the CLEAR Outcome study in the Territory.

Range of relative risk reduction	Reg. Milestone Payment
15%=< RRR<20%	$200M
RRR >= 20%	$300M

33. Nothing in DSE's Statement of Interest conditions the regulatory milestone payment on any particular endpoint in the CLEAR Outcomes Study—MACE-4 or any other. In fact, MACE-4 is not mentioned at all in the Statement of Interest. The Statement of Interest instead provides for DSE to pay a regulatory milestone payment based on the "[r]ange of relative risk

reduction" in the "Cardiovascular Risk Reduction Label . . . as the result of the CLEAR Outcome study." Again, the CLEAR Outcomes Study measured the efficacy of bempedoic acid in reducing the risk of adverse cardiovascular events across ***seven*** different key measures.

34. On November 16, 2018, the parties entered into an exclusivity agreement, in which Esperion agreed to negotiate exclusively with DSE for 45 days regarding a potential exclusive licensing and commercialization deal. Esperion decided to enter into this exclusivity agreement, and to forego potentially lucrative opportunities with other potential partners, in reliance on the financial terms DSE proposed in its Statement of Interest.

35. After signing the exclusivity agreement, the parties began negotiating and drafting the Agreement. The Agreement was an arms-length commercial transaction. Both DSE and Esperion are sophisticated parties, and were represented by experienced counsel in connection with negotiating and drafting the Agreement.

36. On November 19, 2018, Esperion sent DSE a draft of the Agreement consistent with DSE's Statement of Interest. Section 9.2 of Esperion's draft agreement stated that Esperion would be entitled to a regulatory milestone payment based on "Regulatory Approval . . . that includes a Cardiovascular Risk Reduction that correlates to the relative risk reduction" indicated in the table below "based on the CLEAR Outcome study." This draft did not define the term "Cardiovascular Risk Reduction":

9.2. Regulatory Milestone Payment. Esperion will provide DSE with written notice of the achievement of the following regulatory milestone event within ten (10) days after such event has occurred. Esperion shall invoice DSE within thirty (30) days of receipt of such written notice, and DSE shall pay the associated milestone payment within ten (10) days of the receipt of such invoice. This milestone payment shall be payable only once.

Regulatory Milestone Event	Milestone Payment
Grant of the first Regulatory Approval in the DSE Territory of a Licensed Product that includes a Cardiovascular Risk Reduction that correlates to the relative risk reduction indicated below based on the CLEAR Outcome study:	
Greater than or equal to 15% and less than 20%	**$200,000,000**
Equal to or greater than 20%	**$300,000,000**

37. On November 30, 2018, DSE sent Esperion a revised draft of the Agreement. DSE revised Section 9.2 to state that the amount of the regulatory milestone payment "will be reduced by fifty percent (50%) in the event that approved label in the applicable Regulatory Approval in the DSE Territory of a Licensed Product does not meet or exceed the requirements . . . described in Schedule 3.5.1 no. 2":

9.2. Regulatory Milestone Payment. Esperion will provide DSE with written notice of the achievement of the following regulatory milestone event within ten (10) days after such event has occurred. Esperion shall invoice DSE within thirty (30) days of receipt of such written notice, and DSE shall pay the associated milestone payment within ~~ten~~ thirty (~~1~~30) days following ~~of the~~ receipt of such invoice. This milestone payment shall be payable only once.

Regulatory Milestone Event	Milestone Payment*
Grant of the first Regulatory Approval in the DSE Territory of a Licensed Product that includes a Cardiovascular Risk Reduction that correlates to the relative risk reduction indicated below based on the CLEAR Outcome study:	
Greater than or equal to 15% and less than 20%	**$200,000,000***
Equal to or greater than 20%	**$300,000,000***

* Notwithstanding the foregoing, ~~T~~the Parties agree that each of the above mentioned Regulatory Milestone Payment will be reduced by fifty percent (50%) in the event that approved label in the applicable Regulatory Approval in the DSE Territory of a Licensed Product does not meet or exceed the requirements ~~ease the achieved label for the Licensed Product from EMA should fall short of the label language~~ described in **Schedule 3.5.1 no. 2**.

38. DSE added a draft Schedule 3.5.1 to the Agreement, which required a label "indicated to reduce the risk of myocardial infarction, stroke, death and coronary revascularization"—which are the four endpoints that comprise MACE-4 in the CLEAR Outcomes

Study. By the time Esperion and DSE were negotiating the terms of the Agreement in November 2018, the CLEAR Outcomes Study had been ongoing for approximately two years and the endpoints that were being evaluated in the study had already been made public.

Schedule 3.5.1

Licensed Product Label Language for the DSE Territory

1. EU Indication at launch: LDL-C lowering (same as PCSK9i)

- BA(and/or BA/ezetimibe FDC) is indicated in primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:
  - alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated or,
  - in combination with a statin or statin with other lipid lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin
- CV: The effect of BA on cardiovascular morbidity and mortality has not yet been determined.

2. EU Indication post CVOT data: MACE Label (label expansion to label at launch)

BA and BA/ezetimibe FDC is indicated to reduce the risk of myocardial infarction, stroke, death and coronary revascularization in adults with established cardiovascular disease including patients who are statin intolerant.

39. Through these edits, DSE proposed reducing the amount of the regulatory milestone payment owed to Esperion in the event that the label for the Licensed Product did not include a specific indication for MACE-4 risk reduction. In other words, DSE proposed making the amount of Esperion's regulatory milestone payment subject to reduction based on whether the label for the Licensed Product includes a specific indication for MACE-4 risk reduction.[6]

[6] Notably, DSE did not propose making Esperion's ***entitlement*** to a regulatory milestone payment contingent on a label with an indication for MACE-4 risk reduction—let alone on a particular rate of MACE-4 risk reduction. In other words, even in the revised Section 9.2 that DSE proposed and Esperion rejected, DSE did not contemplate that MACE-4 results would play any role in determining Esperion's entitlement to a milestone payment. DSE's current interpretation of the Agreement would give it more favorable treatment than it even sought, unsuccessfully, during the parties' negotiations.

40. ***Esperion rejected DSE's edits to Section 9.2, which were contrary to DSE's Statement of Interest and a transparent attempt to re-trade the parties' deal***. The Statement of Interest did not make the amount of the regulatory milestone payment contingent on an indication for MACE-4 risk reduction—in fact, the Statement of Interest does not refer to MACE-4 at all.

41. On December 11, 2018, Esperion sent DSE another draft of the Agreement, with a revised Section 9.2 requiring DSE to pay Esperion a regulatory milestone payment upon regulatory approval of a Licensed Product that "includes ***cardiovascular risk reduction*** in the label that correlates with the relative risk reduction rate" of at least 15% "as a result of the CLEAR Outcome Study" (emphasis added):

9.2. Regulatory Milestone Payment. Esperion will provide DSE with written notice of the achievement of the following regulatory milestone event within ten (10) days after such event has occurred. Esperion shall invoice DSE within thirty (30) days of receipt of such written notice, and DSE shall pay the associated milestone payment within thirty (30) days following receipt of such invoice. This milestone payment shall be payable only once.

Regulatory Milestone Event	Milestone Payment*
Grant of the first Regulatory Approval in the DSE Territory of a Licensed Product that includes cardiovascular risk reduction in the label that correlates with the relative risk reduction rate indicated below as a result of the CLEAR Outcome Study:	
Equal to or greater than 15% and less than 20%	**$200,000,000**
Equal to or greater than 20%	**$300,000,000**

42. DSE agreed to Esperion's edits to Section 9.2, reflecting the parties' mutual intent and understanding that the regulatory milestone payment is not contingent on the specific reduction of risk of MACE-4. The parties had considered language that would make the amount of the regulatory milestone payment dependent on an indication for MACE-4 risk reduction in the label, but decided not to include that term in the Agreement. Instead, the parties agreed the label needed to include only a "cardiovascular risk reduction" rate of at least 15% in order for Esperion to receive a Regulatory Milestone Payment.

D. In 2019, Esperion And DSE Execute The Agreement.

43. On January 2, 2019, Esperion and DSE executed the Agreement. The Agreement is governed by New York law. *See* Agreement § 14.3.

44. In the Agreement, Esperion granted DSE exclusive rights to "pharmaceutical agent[s] which include[] Bempedoic Acid in any formulation, in any presentation and in any strength" (the "Licensed Product(s)") in the European Economic Area and Switzerland (the "DSE Territory"). Agreement §§ 1.77, 4.1. The Licensed Products include Nilemdo® and Nustendi®. *See id.* § 1.77; *see also id.*, Schedule 1.77.

45. The financial terms of the Agreement mirror the financial terms in DSE's Statement of Interest: DSE agreed to pay Esperion tiered royalties of up to 25% and up to $900 million in milestone payments based on the achievement of certain commercial and regulatory milestones. Agreement § 9.

46. Section 9.2 of the Agreement memorializes the parties' mutual intent, understanding, and agreement that DSE will pay Esperion a regulatory milestone payment in connection with a label for "cardiovascular risk reduction." Specifically, DSE agreed to pay Esperion a "Regulatory Milestone Payment" upon the occurrence of a "Regulatory Milestone Event"—which is defined in the Agreement as the "[g]rant of the first Regulatory Approval in the DSE Territory of a Licensed Product that includes cardiovascular risk reduction in the label that correlates with the relative risk reduction rate" of at least 15% "as a result of the CLEAR Outcome Study." Agreement § 9.2.

47. The Agreement does not define "cardiovascular risk reduction," reflecting the parties' mutual intent and understanding that the term be given its plain and ordinary meaning. If the parties had intended to restrict "cardiovascular risk reduction" to only MACE-4, they could have and would have said so—particularly in light of the fact that the several different endpoints

of the CLEAR Outcomes Study (including MACE-4) had been made public well before the parties negotiated the Agreement. In fact, as described above, the parties specifically considered making Esperion's entitlement to the full Regulatory Milestone Payment contingent on MACE-4, but decided not to add this requirement.

48. The amount of the Regulatory Milestone Payment varies depending on the "cardiovascular risk reduction" rate in the CLEAR Outcomes Study. If the "cardiovascular risk reduction" rate is "[e]qual to or greater than 20%," Esperion is entitled to a Regulatory Milestone Payment of $300 million. Agreement § 9.2. If the "cardiovascular risk reduction" rate is "[e]qual to or greater than 15% and less than 20%," Esperion is entitled to a Regulatory Milestone Payment of $200 million. *Id.*

49. Section 9.2 of the Agreement includes the following table describing the Regulatory Milestone Payment to be paid to Esperion:

Regulatory Milestone Event	Milestone Payment
Grant of the first Regulatory Approval in the DSE Territory of a Licensed Product that includes cardiovascular risk reduction in the label that correlates with the relative risk reduction rate indicated below as a result of the CLEAR Outcome Study:	
Equal to or greater than 15% and less than 20%	**$200,000,000**
Equal to or greater than 20%	**$300,000,000**

50. Section 9.2 also sets out the timing for DSE's payment of the Regulatory Milestone Payment. Under Section 9.2, Esperion "will provide DSE with written notice of the achievement" of the Regulatory Milestone Event within ten (10) days after such event has occurred," and "shall invoice DSE within thirty (30) days of receipt of such written notice." Agreement § 9.2. DSE is then required to pay the Regulatory Milestone Payment "within thirty (30) days following receipt of such invoice." *Id.*

51. On January 4, 2019, Esperion issued a press release announcing the Agreement.

DSE reviewed and approved that press release, which was attached to the Agreement. In the press release, Esperion announced that it had "entered into a licensing agreement with Daiichi Sankyo Europe (DSE) providing DSE with exclusive rights to commercialize bempedoic acid and the bempedoic acid / ezetimibe combination pill in the European Economic Area and Switzerland." Agreement, Schedule 7.3.[7] The press release also described the key financial terms of the Agreement, stating that Esperion is "***eligible to receive a substantial additional regulatory milestone payment*** upon the grant of the Marketing Authorization in the EU for the CV Risk Reduction Label, ***depending on the range of relative risk reduction in the CLEAR Outcomes study***."

52. On January 7, 2019, DSE issued a press release announcing the Agreement. DSE's press release touted Esperion's LDL Treatments as addressing "a significant need for additional treatment options for the large number of patients in Europe with hypercholesterolemia who are not at their target LDL-C level," and stated that the Agreement "will strengthen Daiichi Sankyo's cardiovascular portfolio in Europe."[8] The press release also included the following statement from Rodney Smith, DSE's Head of Medical Affairs, on the LDL Treatments:

> "***We are very pleased to announce this license agreement for bempedoic acid which is a first-in-class treatment that will address a critical unmet need for patients*** who have limited options and who are not reaching their target LDL-cholesterol level," said Rodney Smith, MD, Head of Medical Affairs at Daiichi Sankyo Europe. "***The Esperion team has conducted a robust, 4,000 patient, high-quality development program to establish bempedoic acid as an efficacious and well tolerated therapeutic option and this supports our great confidence in this product that complements and strengthens our current cardiovascular portfolio***, building on the success of LIXIANA®," adds Benoit Creveau, Head of Marketing

[7] *See also Esperion Announces Agreement with Daiichi Sankyo Europe (DSE) to Commercialize Bempedoic Acid in Europe* (Jan. 4, 2019), https://tinyurl.com/54bv7srf.

[8] *Daiichi Sankyo Europe Enters into European Licensing Agreement with Esperion for Bempedoic Acid and the Bempedoic Acid / Ezetimibe Combination Tablet* (Jan. 7, 2019), https://tinyurl.com/yctx6phw.

Cardiovascular at Daiichi Sankyo Europe.

53. Following execution of the Agreement DSE began selling Nilemdo® and Nustendi® in Europe. Under the Agreement, Esperion maintains responsibility for drug development, including clinical trials. *See* Agreement §§ 1.28, 2.1.1. In 2020, Esperion assigned the European Marketing Authorization for Nilemdo® and Nustendi® to DSE, which is now responsible for commercializing these products in Europe. *See* Agreement §§ 3.1, 4.1.3.

E. Esperion Announces The Top-Line Results Of The CLEAR Outcomes Study In December 2022 And Shares The Full Study Results With DSE.

54. The CLEAR Outcomes Study concluded in November 2022. The study demonstrated that patients treated with bempedoic acid had a significantly reduced risk of experiencing major adverse cardiovascular across multiple key measures, or "endpoints." For example, the CLEAR Outcomes Study demonstrated a 27% reduction in non-fatal heart attacks and 23% reduction in the composite of nonfatal and fatal heart attacks. The study also demonstrated a 19% reduction in coronary revascularization (severe blockage of the arteries), 15% reduction in fatal and nonfatal strokes, 15% reduction in MACE-3 (a composite of cardiovascular death, nonfatal heart attacks, or nonfatal stroke), and 13% reduction in MACE-4 (a composite of cardiovascular death, nonfatal heart attacks, nonfatal stroke, or coronary revascularization).

55. On December 7, 2022, Esperion issued a press release announcing the top-line results of the CLEAR Outcomes Study. The press release announced the CLEAR Outcomes Study had "met its primary endpoint, demonstrating statistically significant risk reduction in MACE-4 in patients treated with 180 mg/day NEXLETOL compared to placebo." In the press release, Sheldon Koenig, Esperion's CEO, stated: "With the announcement of these positive topline results, bempedoic acid becomes the first ATP-citrate lyase inhibitor to demonstrate significant and clinically meaningful outcomes results for patients in whom existing lipid lowering therapies fall

short."[9]

56. Shortly after Esperion issued its press release on the top-line results from the CLEAR Outcomes Study, Dr. Wolfgang Schiessl, DSE's Senior Director, PR & Portfolio Communications for Specialty Medicines, congratulated Esperion on the successful results of the CLEAR Outcomes Study. Dr. Schiessl sent an email to Esperion's General Counsel stating: "CONGRATULATIONS!!! ***We are so excited – for the results, for your team.*** Congrats to everyone!"

57. The next day, on December 8, 2022, DSE issued a press release touting the positive results from the CLEAR Outcomes Study. In the press release, DSE announced that "the primary endpoint was met" in the CLEAR Outcomes Study, "demonstrating statistically significant relative risk reduction in major adverse [cardiovascular] events (MACE-4). . . . The initial findings from the data indicate that bempedoic acid is the first oral, ACL inhibitor known to reduce both LDL-C levels and risk of major adverse [cardiovascular] events."[10]

58. DSE's press release also included a statement from Dr. Stefan Seyfried, DSE's Vice President Medical Affairs Specialty Medicines, touting the positive results from the CLEAR Outcomes Study:

> "With 10,000 lives lost everyday to [cardiovascular diseases] in Europe, ***we are truly encouraged by this new data, which demonstrates that bempedoic acid does reduce the risk of serious [cardiovascular] events for patients who are at high-risk of experiencing a heart attack or stroke***," said Dr Stefan Seyfried, Vice President Medical Affairs Specialty Medicines, Daiichi Sankyo Europe GmbH. "We look forward to sharing additional analyses and insights, as well as working closely with the scientific and clinical communities, to better understand how the

[9] *Esperion Announces CLEAR Cardiovascular Outcome Trial of NEXLETOL® (bempedoic acid) Meets Primary Endpoint* (Dec. 7, 2022), https://tinyurl.com/4yuyhu4e.

[10] *Primary endpoint met in the CLEAR Outcomes Trial of bempedoic acid showing statistically significant relative risk reduction in major adverse CV events* (Dec. 8, 2022), https://tinyurl.com/4fvmnvpb.

data can support their care for [cardiovascular disease] patients across Europe."

59. Three days later, on December 11, 2022, Mr. Koenig sent an email to Dr. Jan Van Ruymbeke, DSE's CEO, to align on strategy and next steps in the regulatory process. Mr. Koenig explained that based on the CLEAR Outcomes Study results, ***Esperion "will submit for new, expanded indications in Europe for cardiovascular risk reduction in both primary and secondary prevention each with a relative risk reduction >/= 20%.***" Mr. Koenig further explained that "***[u]nder the terms of our License Agreement, inclusion of a cardiovascular risk reduction of >/= 20% based on CLEAR triggers a milestone payment of $300 million USD***."

60. Esperion executives made clear to DSE that Esperion needed to inform investors about its eligibility for the Regulatory Milestone Payment in light of the CLEAR Outcomes Study results. On December 16, 2022, Benjamin Looker, Esperion's General Counsel, sent an email to Dr. Philipp Hoffman, DSE's Executive Director, Business Development & Licensing, explaining that "***Esperion has received many questions from our investors about what the positive topline results mean with respect to the DSE milestones***." Mr. Looker explained that Esperion planned to communicate to investors in January 2023 that Esperion is "confident that based on the results we expect to receive a milestone from DSE following inclusion of the new indication and corresponding data in the EU label," followed by an announcement in March 2023 of the amount of the regulatory milestone payment Esperion expects to receive. Mr. Looker further noted that Esperion "would be willing to share some of the results [of the CLEAR Outcomes Study] with a limited group at DSE to provide you with an opportunity to confirm our assumptions around the proposed label and corresponding milestone." In response, Dr. Hoffmann said it was "premature to make such a public communication" regarding the milestone payments as DSE had not yet reviewed the results of the CLEAR Outcomes Study. But after further discussion with Esperion,

DSE ultimately agreed to allow Esperion to issue a press release describing its anticipated milestone payments in light of the CLEAR Outcomes Study results, provided that the press release did not specifically identify DSE.

61. On January 9, 2023, Esperion issued a press release: "***Based on the robustness of the CLEAR Outcomes data, the Company believes it would be entitled to receive milestone payments from collaborative partners upon inclusion of cardiovascular risk reduction data in the US and European labels***."[11] This public statement was received by DSE's counsel before Esperion issued the press release.

62. Esperion planned to present the full CLEAR Outcomes Study results at the ACC conference on March 4, 2023, and to publish the results simultaneously in the *New England Journal of Medicine*, a leading peer-reviewed medical journal. Due to embargo restrictions from ACC and the *New England Journal of Medicine*, Esperion could not widely distribute the CLEAR Outcomes Study results before March 4. In response to a request from DSE, Esperion made the full CLEAR Outcomes Study results available to nearly a dozen DSE employees, under strict confidentiality, in January 2023.[12]

63. On January 20, 2023, Dr. JoAnne Foody, Esperion's Chief Medical Officer, presented the CLEAR Outcomes Study results to key DSE personnel, including DSE's Head of Regulatory Strategy and Global Director of Biostatistics. Dr. Foody answered questions from the

[11] *Esperion Outlines Upcoming Milestones and Announces Preliminary Fourth Quarter 2022 Financial Results* (Jan. 8, 2023), https://tinyurl.com/5b8wtn8z.

[12] Esperion had initially offered to share the CLEAR Outcomes Study results with the appropriate group of DSE employees in December 2022. But DSE ignored Esperion's request and failed to provide the list of the employees with whom Esperion should share the results until January 17, 2023. As a result, Esperion was unable to share the CLEAR Outcomes Study results with DSE before January 20, 2023.

DSE attendees, and after the presentation, Dr. Foody shared her slides reflecting the CLEAR Outcomes Study results with the DSE attendees.

64. After Dr. Foody's presentation, on February 15, 2023, DSE asked Esperion to provide the patient-level data underlying the CLEAR Outcomes Study. Although DSE's request was unusual and required Esperion to re-allocate resources to obtain the patient-level data from the CLEAR Outcomes Study and prepare this data for DSE's review, Esperion complied with the request and made this data to key DSE employees under strict confidentiality.

F. In March 2023, Esperion Presents The Full CLEAR Outcomes Study Results, Which Demonstrate Bempedoic Acid Significantly Reduces Cardiovascular Risk.

65. The results of the CLEAR Outcomes Study were published on March 4, 2023 in the prestigious *New England Journal of Medicine*. At the same time, Esperion presented the results at the ACC conference on March 4, 2023. The published results conclude: "The observed lower incidence of cardiovascular events suggests that bempedoic acid is among the medications that lower the LDL cholesterol level and have clinically meaningful cardiovascular benefits."

66. The CLEAR Outcomes Study results received considerable media attention—in the medical community, pharmaceutical industry, and the broader public. The CLEAR Outcomes Study results were covered in more than 500 print, trade, and broadcast media pieces—including in *The New York Times*, *The Wall Street Journal*, and *The Washington Post*—garnering over a billion total impressions (equivalent to approximately $200 million in paid advertising).

67. The medical community recognized the CLEAR Outcomes Study results as an unprecedented breakthrough in the treatment of LDL cholesterol in statin intolerant patients. Following the ACC conference, Esperion conducted a survey of health care providers, which found that an overwhelming 98% of providers had a positive to highly positive reaction to the CLEAR Outcomes Study results. In addition, the results of the CLEAR Outcomes Study have been touted

by leading medical publications and organizations:

- An accompanying editorial published in the *New England Journal of Medicine* proclaimed that following the CLEAR Outcomes Study results, "[b]empedoic acid has now entered the list of evidence-based alternatives to statins for primary and secondary prevention in patients at high cardiovascular risk." It further described the results as "compelling" and predicted that they "***will and should increase the use of bempedoic acid in patients with established atherosclerotic vascular disease and in those at high risk for vascular disease who are unable or unwilling to take statins***."

- An article for the Cleveland Clinic touts that "[t]he non-statin lipid-lowering medication bempedoic acid (Nexletol®) has ***demonstrated a significant reduction in the risk of cardiovascular events in a large outcomes study of statin-intolerant patients.***" The first-named author of the published CLEAR Outcomes Study results, Dr. Steven Nissen, explained that the results "***add bempedoic acid to the group of LDL cholesterol (LDL-C)-lowering medications that have shown clinically meaningful cardiovascular benefits***" and that bempedoic acid "now represents a very viable alternative for patients who need their cholesterol to be lowered but cannot or will not take statins." The article further quotes Michael Lincoff, MD, a co-author on the published results, who said that the data show "that reduction of LDL cholesterol meaningfully diminishes the risk of cardiac events in high-risk patients."

- Following the publication of the results of the CLEAR Outcomes Study, the International Lipid Expert Panel (ILEP) published positive "recommendations for the use of bempedoic acid in the management of lipid disorders and cardiovascular risk."

68. In the four weeks after the announcement of the results of the CLEAR Outcomes Study, the number of prescriptions written for patients switching to or starting the LDL Treatments increased by 88%.

G. In March 2023, DSE Reneges On Its Contractual Commitments And Tells Esperion It Will Not Pay The Contractually-Required Regulatory Milestone Payment.

69. On March 4, Esperion issued a press release announcing the full CLEAR Outcomes Study results and informing its shareholders of its entitlement to the Regulatory Milestone Payment. The press release stated: "The Company believes that it remains on track to submit regulatory filings to the FDA and EMA in 1H 2023. Based on the robustness of the CLEAR

Outcomes data, ***the Company believes it would be entitled to receive $300 million in partner milestone payments upon inclusion of certain required cardiovascular risk reduction data in the EU label,*** for which payment is tied to the magnitude of the risk reduction percentage included in the label (among other requirements) and ranges from $200 to $300 million."

70. Four days later, on March 8, 2023, Andreas Berger, DSE's Senior Director, Regional Management, sent an email to Esperion executives stating: "We have only recently received and are still analyzing the data underlying the CLEAR study but ***based on the results that have been reported to date, we do not agree that Daiichi Sankyo Europe will owe a milestone payment under our agreement***. We appreciate you to provide the basis for Esperion's different opinion in this regard."

71. Later that day, on March 8, Patricia Vanston, Esperion's Executive Director, Sales Learning and Development & Alliance Management, responded to Mr. Berger's email and explained Esperion's position that it was entitled to the Regulatory Milestone Payment: "Section 9.2 of the LCA states that Esperion will be entitled to receive a $300 million milestone payment from DSE upon the inclusion of 'cardiovascular risk reduction' in the EU label that corelates with a relative risk reduction rate of 20% or more. ***In the CLEAR trial, Nexletol significantly reduced the risk of myocardial infarction by 23% so upon the inclusion of that data point in the EU label, Esperion will be entitled to receive $300 million.*** If you disagree, we would appreciate your explanation why."

72. On March 14, 2023, DSE expressly reneged on its contractual commitment to pay Esperion the Regulatory Milestone Payment. In an email to Ms. Vanston, Mr. Berger stated: "the CLEAR Outcomes Study showed that Nexletol reduces MACE-4 – the primary endpoint of the Study – by 12,98%. ***This is not sufficient to trigger any regulatory milestone payment under***

section 9.2 of the LCA irrespective of what may be included in the EU label."

73. At no point in the weeks after the release of the top-line CLEAR Outcomes Study results on December 7, 2022, or after Esperion made the full CLEAR Outcomes Study results available to DSE personnel in January 2023, did DSE say that the Regulatory Milestone Payment was contingent on the composite risk reduction rate for MACE-4.

74. On March 14, 2023, Mr. Looker, Esperion's General Counsel, responded to Mr. Berger, explaining Esperion's disagreement with DSE's position and its obligation to disclose DSE's repudiation to the market: "***We received your note below and strongly disagree with your interpretation of the LCA. Please note that as a public company in the US (and in connection with any potential fundraising), we may be required to publicly disclose your position in this matter (while noting our strong disagreement).*** In any such disclosure, we would also be clear that we will be fully prepared to enforce our contractual rights at the appropriate time against DSE and ensure DSE complies with its contractual commitments."

75. Mr. Berger responded the next day, reaffirming DSE's repudiation and acknowledging Esperion's obligation to disclose DSE's repudiation to investors.

76. On March 20, 2023, Sheldon Koenig, Esperion's CEO, had a call with Dr. Jan Van Ruymbeke, DSE's CEO. During the call, Dr. Van Ruymbeke confirmed DSE's position that Esperion was not entitled to the Regulatory Milestone Payment because the risk reduction for MACE-4 in the CLEAR Outcomes Study was less than 15%. Mr. Koenig explained that the relevant provision of the Agreement does not refer to MACE-4, and instead provides for the Regulatory Milestone Payment based on "cardiovascular risk reduction." Mr. Koenig asked Dr. Van Ruymbeke to reconsider his position and to get back to him by March 22, 2023. The two CEOs spoke again on March 22, and Dr. Ruymbeke confirmed that DSE's position remained

unchanged and that DSE would not pay Esperion the Regulatory Milestone Payment.

77. DSE's position is flatly inconsistent with the plain and unambiguous language of the Agreement. Section 9.2 requires DSE to pay the Regulatory Milestone Payment upon inclusion of "cardiovascular risk reduction in the label that correlates with [a] relative risk reduction" of at least 15% in the CLEAR Outcomes Study. The CLEAR Outcomes Study demonstrated a relative risk reduction rate over 15% for many of the studied endpoints—including a 27% reduction in the risk of nonfatal myocardial infarction (heart attacks), a 23% reduction rate for the composite of nonfatal and fatal myocardial infarction (heart attacks), 15% reduction in the risk of fatal and nonfatal stroke, and 19% reduction in the risk of coronary revascularization, and 15% reduction rate for MACE-3, a composite of three major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke). The ordinary meaning of "cardiovascular risk reduction" unambiguously includes a reduction in the risk of heart attacks, stroke, and coronary revascularization.

78. If the parties had intended to limit the Regulatory Milestone Payment trigger to *only* a reduction in the risk of MACE-4—as opposed to the broader "cardiovascular risk reduction" language they agreed to—they would have said so in the Agreement. And in fact, that is just what DSE tried to do, unsuccessfully: during the negotiation of the Agreement, DSE proposed making the amount of the Regulatory Milestone Payment subject to a 50% reduction based on the inclusion of MACE-4 risk reduction in the label. But Esperion rejected this term, and DSE agreed—reflecting the parties' mutual intent and understanding that the Regulatory Milestone Payment was not dependent on MACE-4 risk reduction specifically and, instead, on "cardiovascular risk reduction."

79. On information and belief, Daiichi Sankyo's business recently has faced uncertain

business prospects and significant financial pressure. For example, Daiichi Sankyo has been unable to bring a key drug candidate, a treatment for acute myeloid leukemia (AML), to market. The FDA first rejected Daiichi Sankyo's AML drug candidate in 2019 based on concerns about the reliability of the clinical trial data. The FDA recently delayed approval of its treatment for AML again. On information and belief, facing setbacks in its own business, Daiichi Sankyo recently began searching for ways to get out of its obligation to make a $300 million payment to Esperion. As evidenced by private and public statements that it made and approved, DSE understood the highly successful CLEAR Outcomes Study results meant it was only a matter of time before it owed $300 million to Esperion. But after DSE discovered the risk reduction rate for one of the endpoints in the CLEAR Outcomes Study—MACE-4—was less than 15%, it saw an opportunity to renege on its contractual obligation to pay hundreds of millions of dollars to Esperion. DSE's newfound position that Esperion is entitled to the Regulatory Milestone Payment only if the MACE-4 risk reduction rate is at least 15% is nothing more than a pretext to circumvent its payment obligations.

H. DSE's Repudiation Of Its Contractual Obligations Has Harmed, And Continues To Harm, Esperion.

80. On information and belief, DSE, knowing the importance of the Regulatory Milestone Payment for Esperion, timed its repudiation to put maximum pressure on Esperion and force Esperion back to the bargaining table to renegotiate the terms of the deal. DSE was aware that Esperion would have to disclose DSE's refusal to make the milestone payment to the market: Esperion executives had repeatedly told DSE that they needed to respond to investor questions about what the CLEAR Outcomes Study results meant for the regulatory milestone payment from DSE and would have to "***publicly disclose*** [DSE's] ***position in this matter***" given Esperion's disclosure obligations "as a public company in the US."

81. DSE's repudiation of its contractual obligations caused immediate and substantial harm to Esperion. As DSE had been warned, under the federal securities laws Esperion was required to disclose to shareholders DSE's repudiation of its contractual obligation to pay a $300 million milestone payment. In accordance with its legal obligations and as a result of a pending securities offering, on March 15, 2023, Esperion filed a Form 8-K with the U.S. Securities and Exchange Commission disclosing DSE's refusal to pay the milestone payment required under the Agreement. The Form 8-K states:

> ***The Company has had communications with Daiichi Sankyo Europe (DSE) regarding potential milestone payments in which DSE has conveyed that it disagrees with the Company's assessment that the CLEAR Outcomes data would support the Company's right to receive any milestone payments*** upon inclusion of certain required cardiovascular risk reduction data in the EU label, because the CLEAR Outcomes study showed a 12.98% reduction in MACE-4, the primary endpoint of the trial. The Company strongly disagrees and continues to believe that, pursuant to Section 9.2 of the Company's license and collaboration agreement with DSE, which refers only to cardiovascular risk reduction and not to any primary endpoint, it would be entitled to receive such payment upon inclusion of cardiovascular risk reduction in the EU label that correlates with a relative risk reduction rate of at least 20%, based on the CLEAR Outcomes trial demonstrating a significant reduction of fatal and non-fatal myocardial infarction by 23%. If necessary, the Company intends to enforce its contractual rights and seek the milestone payments it believes it is entitled to. Even if the Company is successful in enforcing its rights, there could be a delay in the Company's receipt of the milestone payments as a result of any dispute relating to such payments. Any failure to receive or any delay in receipt of the milestone payments may significantly impact the Company's future capital needs.[13]

82. The market's reaction to news of DSE's repudiation was swift and certain. On March 16, the day after Esperion filed its Form 8-K, Esperion's stock price fell 54%, from approximately $3.98 per share to approximately $1.82 per share.[14] Esperion's stock has continued

[13] Esperion Therapeutics, Inc., Form 8-K (Mar. 15, 2023), https://tinyurl.com/7r5ewj9j.

[14] *Esperion (ESPR) Plummets 54% Over Milestone Payment Row*, NASDAQ (Mar. 17, 2023), https://tinyurl.com/mvkbfw4d.

to fall and has remained under $2 per share since Esperion disclosed DSE's refusal to pay the milestone payments under the Agreement. Today, Esperion's stock price is approximately $1.36 per share, representing an approximately 65% decline since the disclosure of DSE's repudiation of its contractual obligations.

83. Further, on information and belief, DSE was aware that Esperion was planning to close an offering in March 2023 to raise capital for its business. DSE repudiated its contractual obligation on the eve of Esperion's closing of its offering—and after news of DSE's repudiation became public, Esperion was forced to renegotiate its offering to less favorable terms and reduce the amount of its offering.

84. Esperion continues to suffer harm as a result of DSE's bad-faith repudiation of its contractual obligations.[15]

CLAIMS FOR RELIEF

COUNT I
(Declaratory Relief)

85. Esperion repeats and realleges the foregoing paragraphs as if fully set forth herein.

86. The Court has the power to grant declaratory relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. As a result of the acts described in the preceding paragraphs, a case of actual controversy within this Court's jurisdiction exists between the parties concerning the interpretation of the Agreement and Esperion's eligibility to receive the Regulatory Milestone Payment under Section 9.2 of the Agreement. A declaratory judgment is necessary and appropriate to resolve this dispute and adjudicate the rights of the parties under the Agreement.

[15] Esperion reserves the right to seek leave to amend its pleading to assert damages claim(s) arising from DSE's repudiation of its contractual obligations and any other misconduct uncovered in discovery.

87. Esperion entered into a valid, binding, and enforceable agreement with DSE, the Agreement, dated January 2, 2019, in which Esperion granted an exclusive license to DSE in the European Economic Area and Switzerland in exchange for consideration, including the Regulatory Milestone Payment.

88. Esperion has performed and continues to perform all material conditions, covenants, and promises in the Agreement.

89. Section 9.2 of the Agreement requires DSE to make a Regulatory Milestone Payment to Esperion upon the "[g]rant of the first Regulatory Approval in the DSE Territory of a Licensed Product that includes cardiovascular risk reduction in the label that correlates with" a certain "relative risk reduction rate" as a "result of the CLEAR Outcome Study." Specifically, upon Regulatory Approval that "includes cardiovascular risk reduction in the label that correlates with the relative risk reduction rate" that is "[eq]ual to or greater than 15% and less than 20%," Esperion is entitled to a $200 million Regulatory Milestone Payment. Agreement § 9.2. If the label includes "cardiovascular risk reduction" that correlates to a "relative risk reduction rate" that is "[e]qual to or greater than 20%," Esperion is entitled to a $300 million Regulatory Milestone Payment. *Id.*

90. The CLEAR Outcomes Study demonstrated a "cardiovascular risk reduction" greater than 20%. Specifically, the Study demonstrated (1) a 27% reduction in the relative risk of nonfatal myocardial infarction (heart attacks) and (2) a 23% risk reduction rate for the composite of both fatal and non-fatal myocardial infarction in patients taking bempedoic acid compared to those taking a placebo.

91. In addition, the CLEAR Outcomes Study demonstrated a cardiovascular risk reduction greater than 15% and less than 20% for several endpoints. Specifically, the Study

demonstrated (1) a 15% reduction in the relative risk of fatal and nonfatal stroke, (2) 19% reduction in the relative risk of coronary revascularization, and (3) 15% reduction in the relative risk of MACE-3, a composite of three major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke), in patients taking bempedoic acid compared to those taking a placebo.

92. Because the CLEAR Outcomes Study demonstrated that the relative risk reduction rate of bempedoic acid exceeds 20%, Esperion is entitled to a $300 million Regulatory Milestone Payment upon Regulatory Approval of an amended label including cardiovascular risk reduction. *See* Agreement § 9.2.

93. Even though the CLEAR Outcomes Study demonstrated a "cardiovascular risk reduction" greater than 20%, DSE has repudiated its obligation to pay Esperion any Regulatory Milestone Payment upon Regulatory Approval.

94. DSE has informed Esperion that it does not intend to make any Regulatory Milestone Payment to Esperion because the CLEAR Outcomes Study demonstrated only a 12.98% reduction in MACE-4.

95. DSE's position is contrary to the plain and unambiguous language of the Agreement. It is also contrary to the Agreement's drafting history and other parol evidence, and amounts to bad faith.

96. Section 9.2 of the Agreement requires only that the CLEAR Outcomes Study demonstrate a "relative risk reduction rate" of 15% or greater in "cardiovascular risk reduction" for Esperion to be entitled to a Regulatory Milestone Payment. Section 9.2 does not even mention MACE-4—let alone make Esperion's eligibility for the Regulatory Milestone Payment contingent on a specific risk reduction rate for MACE-4. The parties specifically considered a similar

proposal from DSE tied to MACE-4 results, and then expressly rejected it.

97. An actual, justiciable, and substantial controversy exists between Esperion and DSE regarding the interpretation of the Agreement and Esperion's right to Regulatory Milestone Payments thereunder.

98. The parties' legal interests are adverse because DSE has repudiated its obligation under the Agreement and argues that Esperion is not entitled to the Regulatory Milestone Payment, while Esperion maintains that it is entitled to the Regulatory Milestone Payment. The controversy is of sufficient immediacy and reality to warrant declaratory relief under 28 U.S.C. § 2201. Further, Esperion and DSE are currently finalizing their submission to the European Medicines Agency ("EMA") requesting a full indication change for Esperion's LDL Treatments, and Esperion could obtain Regulatory Approval as early as the first half of 2024, which would immediately entitle Esperion to a Regulatory Milestone Payment.

99. The Court may exercise its discretion to grant declaratory relief immediately, as this dispute presents a pure question of law; Esperion's entitlement to the Regulatory Milestone Payment under Section 9.2 of the Agreement is a matter of contract interpretation.

100. Absent resolution of this controversy, Esperion anticipates that DSE will continue to refuse to pay the Regulatory Milestone Payment to Esperion as required by the Agreement. Such refusal has already and will continue to cause harm and damage to Esperion by causing investors to question Esperion's financial position and its ability to enhance shareholder value. Since Esperion disclosed DSE's repudiation of its Regulatory Milestone Payment obligation on March 15, 2023, Esperion's stock has plummeted in value from $3.98 per share before the disclosure to $1.36 per share on May 3, 2023. This represents an approximately 65% decrease in Esperion's stock price in the past seven weeks.

101. The requested declaratory relief will serve a useful purpose in settling the legal issues involved because it will determine whether Esperion is entitled to a Regulatory Milestone Payment under the circumstances presented here, and whether DSE's repudiation of the milestone payment obligation constitutes a breach of the Agreement.

102. For the same reasons, the requested declaratory relief will finalize the controversy between the parties. DSE's repudiation of the milestone payment obligation is premised solely on an incorrect interpretation of the Agreement. Were this Court to declare that DSE's interpretation of the Agreement is incorrect and that Esperion's interpretation is correct, DSE will no longer be able to justify its refusal to pay the Regulatory Milestone Payment on the basis of its incorrect interpretation of the Agreement.

103. The requested declaratory relief will prevent further injury to Esperion caused by DSE's repudiation of its obligation to pay Esperion the Regulatory Milestone Payment as required under the Agreement, including by dispelling investor concerns about Esperion's business prospects and its ability to meet its financial obligations.

104. There is no better or more effective remedy than a federal court declaratory judgment action. The parties' dispute is solely a matter of competing interpretations of their obligations under the Agreement, which this Court is best positioned to resolve.

105. No concerns regarding judicial efficiency or judicial economy counsel against exercise of the Court's discretion here.

106. Esperion is entitled to a declaratory judgment that the phrases "cardiovascular risk reduction" and "relative risk reduction " as used in Section 9.2 of the Agreement do not refer solely to the MACE-4 composite endpoint in the CLEAR Outcomes Study.

107. Esperion is entitled to a declaratory judgment that the phrases "cardiovascular risk

reduction" and "relative risk reduction" as used in Section 9.2 of the Agreement include a reduction in the risk of nonfatal myocardial infarction (heart attacks), the composite of nonfatal and fatal myocardial infraction, fatal and nonfatal stroke, coronary revascularization, and MACE-3 in the CLEAR Outcomes Study.

108. Esperion is entitled to a declaratory judgment that a reduction in the risk of nonfatal myocardial infarction and/or the composite of nonfatal and fatal myocardial infraction greater than 20% in patients using bempedoic acid in the CLEAR Outcomes Study entitles Esperion to a $300 million Regulatory Milestone Payment, upon Regulatory Approval of an amended label including cardiovascular risk reduction. In the alternative, Esperion is entitled to a declaratory judgment that a reduction in the risk of fatal and nonfatal stroke, coronary revascularization, and/or MACE-3 equal to or greater than 15% and less than 20% in patients using bempedoic acid in the CLEAR Outcomes Study entitles Esperion to a $200 million Regulatory Milestone Payment, upon Regulatory Approval of an amended label including cardiovascular risk reduction.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Esperion respectfully demands the following relief:

a. A declaratory judgment that the phrases "cardiovascular risk reduction" and "relative risk reduction " as used in Section 9.2 of the Agreement do not refer solely to the MACE-4 composite endpoint in the CLEAR Outcomes Study.

b. A declaratory judgment that the phrases "cardiovascular risk reduction" and "relative risk reduction" as used in Section 9.2 of the Agreement include a reduction in the risk of nonfatal myocardial infarction (heart attacks), the composite of nonfatal and fatal myocardial infraction, fatal and nonfatal stroke, coronary revascularization, and MACE-3 as reported in the CLEAR Outcomes Study;

c. A declaratory judgment that a reduction in the risk of nonfatal myocardial infarction and/or the composite of nonfatal and fatal myocardial infraction greater than 20% in patients using bempedoic acid in the CLEAR Outcomes Study entitles Esperion to a $300 million Regulatory Milestone Payment, upon Regulatory Approval of an amended label including cardiovascular risk reduction. In the alternative, Esperion is entitled to a declaratory judgment that a reduction in the risk of fatal and nonfatal stroke, coronary revascularization, and/or MACE-3 equal to or greater than 15%

and less than 20% in patients using bempedoic acid as reported in the CLEAR Outcomes Study entitles Esperion to a $200 million Regulatory Milestone Payment, upon Regulatory Approval of an amended label including cardiovascular risk reduction.

d. Esperion's reasonable costs and expenses in bringing this action, including attorneys' fees; and

e. Such other and further relief as this Court deems just and proper.

JURY DEMAND

Esperion hereby demands a jury trial as to all claims so triable.

Dated: New York, New York
May 4, 2023

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